To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: TSCA Reform TA on Two Questions

Dimitri,
Thank you for the TA request. We're preparing a response to the first question, including suggested language to ensure that if EPA determines that a new chem is "likely to meet safety standard", they can commence manufacturing without having to wait for the review period to expire.

Regarding the second question, any time available tomorrow afternoon, Tues, Oct 6 for a call? We have concerns on the articles language and the level of analysis it could be read to require prior to regulating. Best, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, October 02, 2015 3:44 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: Two Questions

Sven,

Wanted to run two things by you all and see if there were any concerns or suggestions. First is on pmn approval. My understanding is under current law EPA essentially silently approves pmn's by allowing the 90 day clock to run. The bill forces EPA to make a determination of likely to meet the safety standard in order for a new chemical to be granted a pmn which I know is a big deal for my colleagues on this email. That being said, the way I had intended/presumed the language to work is that if EPA found a new chemical likely to meet on the 30th day, you would have your approval and not have to wait the next two months to move forward in the process you would be good to go. Some folks have raised concern that their reading of the bill would require, even after EPA approval, waiting for the 90 day clock to expire while nothing is happening. What is EPA's interpretation and if you all read the language as requiring you to not grant a pmn until the 90 day time period expires is there a small technical tweak you can suggest to fix that?

Second question is based on conversations you have had with regards to the section 6 articles language. This may need to be a phone conversation but I was given some language and wanted to know if you all viewed it as a problem or as a big expansion to what is already in the bill? As we have previously discussed, the articles language is largely codifying EPA current practice, not designed to create new regulatory hurdles you all cannot overcome; would this language if included create some new burden?

Proposed Amendment -- Section 8 (Amending TSCA § 6(d)(2)(A))
(pages 247, lines 17-25; page 248, lines1-5):

"(iii) shall, in selecting among prohibitions and other restrictions, apply such prohibitions or other restrictions to articles containing the chemical substance only to the extent necessary to address the identified risks from exposure to the chemical substance from the article or category of articles, in order to determine that the chemical substance meets the safety standard.

No urgency to get this back today or over the weekend but early next week would be great.

Thanks,

Dimitri

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/6/2015 1:09:15 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: RE: TSCA Reform TA on Two Questions

Dimitri – 1pm today would be best for us. Please call Personal Phone / Ex. 6 code Personal Phone / Ex. 6. Just let me know if need to shift the time. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, October 05, 2015 7:55 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: RE: TSCA Reform TA on Two Questions

Thanks Sven – if we could get that TA tomorrow that would be great. Also I should have some time for a call tomorrow afternoon either around 1 or later around 4.

Let me know what works best and thanks again.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, October 05, 2015 2:42 PM
To: Karakitsos, Dimitri (EPW)
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: TSCA Reform TA on Two Questions

Dimitri,
Thank you for the TA request. We're preparing a response to the first question, including suggested language to ensure that if EPA determines that a new chem is "likely to meet safety standard", they can commence manufacturing without having to wait for the review period to expire.

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Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, October 02, 2015 3:44 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: Two Questions

Sven,

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No urgency to get this back today or over the weekend but early next week would be great.

Thanks,

Dimitri

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/5/2015 6:41:48 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]
CC: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]; Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: TSCA Reform TA on Two Questions

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From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, October 02, 2015 3:44 PM
To: Kaiser, Sven-Erik
Cc: Black, Jonathan (Tom Udall); Freedhoff, Michal (Markey)
Subject: Two Questions

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Dimitri

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/1/2015 9:22:44 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: FYI...

Thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, October 01, 2015 5:21 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: FYI...

Senate TSCA bill debate held up by Burr

By Darren Goode

10/01/2015 05:01PM EDT

Sen. Richard Burr's yearlong push to reauthorize the Land and Water Conservation Fund is the last big obstacle to a bill that would overhaul federal oversight of dangerous chemicals from coming to the Senate floor early next week, according to sources closely following the talks.

Burr is a co-sponsor of a bipartisan bill from Sens. Tom Udall (D-N.M.) and David Vitter (R-La.) to update the 1976 Toxic Substances Control Act, which is backed by more than half the Senate and has the official blessing of both parties. But the North Carolina Republican is effectively holding up efforts to quickly bring the measure to the floor under a unanimous consent agreement while he seeks a vote on an amendment permanently reauthorizing LWCF, which expired Wednesday.

"My understanding is that there are one or more unrelated holds in which people are trying to use the prospect of the TSCA bill moving in which to leverage to try to do something unrelated and that there is an effort being made to try to clear those holds," Sen. Sheldon Whitehouse (D-R.I.) told POLITICO.

Whitehouse didn't specifically reference Burr, although other sources did.

Other Republicans who previously had holds on the TSCA bill or who were seeking amendments on unrelated items have lifted their opposition. That includes Sen. John Hoeven's effort to get a vote to end the crude oil export ban and Sen. Dean Heller's desire to have a vote on EPA's mercury rule, sources said.

Burr briefly received enough Senate votes to permanently reauthorize the LWCF under an amendment to a bill approving the Keystone XL pipeline in January. But the amendment eventually fell one vote short due to concern that it would become a poison pill in the House because it wasn't paid for.

A Burr spokeswoman could not immediately confirm that the North Carolina Republican still had a hold on TSCA and did not have an update on the talks.

Proponents aim to bring the TSCA bill to the floor as early as Tuesday. Sen. Joe Manchin (D-W.Va.) told reporters he was planning to go to the floor that day with Udall to talk about the issue.

Meanwhile, negotiations have successfully ended on changes to the underlying TSCA bill.

"I think that we've worked through it and I'm hoping that those who have concerns with it, they're more comfortable, let's put it that way," Manchin said.

He was referring to Senate Environment and Public Works ranking member Barbara Boxer (D-Calif.), who has led opposition to the bill mainly over concern that it would trump state toxic controls, especially in California.

Boxer called a meeting with fellow EPW Democrats Wednesday afternoon to announce that, while she won't be supporting the current version of the Senate bill, she won't hold it up, sources said.

Boxer had previously pushed to have the Senate take up a far narrower House-passed bill that would not preempt toxic controls in California and other states. But she has now agreed to having the Senate bill as the vehicle to take into bicameral talks with the House, sources said.

Sen. Ed Markey (D-Mass.) and Senate Minority Whip Dick Durbin (D-Ill.) worked together to update the version the EPW panel approved 15-5 in April that "strengthens certain aspects of the bill," said one Senate Democratic aide, who declined to specify the changes.

Markey was one of the five Democrats who voted against the bill in committee, but he will be supporting the version that goes to the floor, the aide said.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/30/2015 1:00:52 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Emailing: S.697 - Substitute - Confidential Draft - Administration Review - V.1.0

Got it- thanks

On Sep 30, 2015, at 8:39 AM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Please find attached the draft version of the Substitute that we plan to circulate on the Hotline.

We would appreciate your attention to a Statement of Administration Policy as soon as possible. We hope to have agreement to proceed to the Substitute as early as today, although that is subject to several other factors.

The only change that has occurred from the previous version you have seen [Orion v.11.0] is the added Sec.29 at the end. This language was negotiated and agreed to by Sens. Reid, Heller and Whitehouse.

Your message is ready to be sent with the following file or link attachments:

S.697 - Substitute - Confidential Draft - Administration Review - V.1.0

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.
<S.697 - Substitute - Confidential Draft - Administration Review - V.1.0.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/29/2015 2:49:58 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Confidential updated language

Jonathan, thanks for Orion 11. We're working on the SAP. Please let us know when hotlining. Best, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Tuesday, September 29, 2015 10:36 AM
To: Bauserman, Trenton; Billingsley, Tara; Vaught, Laura; Kaiser, Sven-Erik
Cc: Karakitsos, Dimitri (EPW)
Subject: Confidential updated language

Please be aware that this is not final, but it represents the latest package that has been shared among Senate lead offices.

We are still trying to resolve some issues (some non-germane and other very minor).

But it is very possible that the bill could be put on the hotline and we move to TSCA quickly. We want you to be able to issue the SAP.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/23/2015 9:04:36 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: Sen. Udall TSCA TA on NRDC Blog

Jonathan,
We're going through the blog and will be in position to talk with you by this Fri, Sept 25. Please let me know if you want to schedule a call on Friday or next week. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/16/2015 10:18:27 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Imports, FYI...

Prospects for action next week?

On Sep 16, 2015, at 6:18 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

I can wait till you're available. No rush

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 6:08 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: Re: Imports, FYI...

Ok, I'll get it started. I'm out Fri-Mon so others will handle. Thanks ,
Sven

On Sep 16, 2015, at 5:54 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Friday, Monday, something like that.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 5:52 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Imports, FYI...

How near?

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:50 PM
To: Kaiser, Sven-Erik
Subject: RE: Imports, FYI...

I'd like to have a call on this issue in the near-future. Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 5:48 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Imports, FYI...

thanks

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:45 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: Imports, FYI...

Daniel Rosenberg's Blog

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

Print this page

Posted September 16, 2015

Tags:
cancer, carcinogens, chemcials, publichealth, righttoknow, saferchemicalshealthyfamilies, takeouttoxics, toxicchemicals, TSCA

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The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue to overstate (see also here) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the Safer Chemicals Healthy Families coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently

exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a

particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet --regarding the reasonable potential of exposure to the fibers from any article or category of articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erinonite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

Or consider EPA's recent significant new use rule for benzidine dyes, finalized last December. EPA identified the breakdown products of benzidine dyes as known human carcinogens, and referenced evidence of potential exposure from the dyes in clothes and textile-related uses. Based on the available information EPA had regarding the chemical's toxicity, and the potential for exposure from clothing, footwear and textiles, EPA

imposed a new use notice requirement for any new use of benzidine dyes, and lifted the articles exemption, making the notice requirement applicable to potential new uses of benzidine dyes in articles (products) to be imported into the U.S.

Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the chemical -- for example, other categories of articles for which EPA did not already have some exposure information -- a court might rule that EPA did not have the authority to extend notice requirements to those uses, despite the agency's concerns about the chemicals' potential harm to health or the environment. Relying on the argument that EPA *might* prevail in such a lawsuit as an excuse for not flatly rejecting the proposed weakening of current law is simply irresponsible. The new Senate language in fact makes it more likely that articles containing chemicals of concern to EPA will be imported into the U.S. It is also directly contrary to what the drafters of the original TSCA intended.

In the Committee report filed when TSCA was originally passed in 1976, the Senate Commerce Committee (which handled TSCA then) noted the heightened concern about chemicals causing cancer, birth defects and other harms to health and the environment and the limited scope of other existing laws that touched in various ways on the problem of chemical pollution including the Clean Air Act, Clean Water Act, Occupational Safety and Health Act and the Consumer Product Safety Act: "None of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins. The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest....If hazards are to be discovered and prevented prior to the manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision... the pre-market notification provisions of the committee bill forms [sic] the backbone of the preventive aspects of health protection sought by this legislation."

EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
- Toluene Diisocyanates (TDI) and related compounds - that are dermal and inhalation sensitizers that can cause asthma and lung damage;
- Hexabromocyclododecane (HBCD) - a flame retardant ingredient linked to hormone disruption, aquatic toxicity and a possible reproductive toxin that is already subject to authorization (meaning likely phase out) under the European Union's REACH regulation and a global phase-out under the Persistent Organic Pollutants (POPs) treaty;
- Polybrominated Diphenyl Ethers (PBDEs) - another group of flame retardants that are persistent, bioaccumulative and toxic.

In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- *exactly what the agency should be doing under TSCA*. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and

risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

Efforts to limit EPA's ability to obtain information about potential new uses of chemicals of concern in products before they reach the market, are swimming against the tide of chemical regulation around the world, as well as consumer satisfaction and acceptance. Public demand (and therefore retailer demand) to know what chemicals are used in products is not going away. Contrary to the hopes of many in industry who are salivating for passage of the Udall/Vitter bill, flawed TSCA reform legislation will not stem that tide. EPA's existing authority to obtain information about potential new uses of chemicals of concern before they are imported into the U.S. in products is a modest and effective method of ensuring some degree of protection for the public. Constraining EPA's authority to target articles for significant new use notification is the industry's over-reaction to EPA's exercising its authority in a handful of instances. But increasing the burden on EPA and limiting its ability to take these steps will be met with its own reaction - more action at the state level, and in the marketplace - something these same industries should seriously contemplate before taking a step that could easily backfire.

Members of Congress who consider themselves supporters and protectors of EPA's role in protecting public health and the environment should carefully consider (or reconsider) their support for legislation containing this very problematic provision. If the Senate does not have the fortitude to tell these companies that this special interest provision to weaken current TSCA is an early Christmas gift that they cannot have, then the White House should make clear that it needs to come out of the bill before TSCA reform legislation reaches the President's desk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/16/2015 10:07:55 PM
To: Black, Jonathan (Tom Udall) [Jonathan_Black@tomudall.senate.gov]
Subject: Re: Imports, FYI...

Ok, I'll get it started. I'm out Fri-Mon so others will handle. Thanks ,
Sven

On Sep 16, 2015, at 5:54 PM, "Black, Jonathan (Tom Udall)" <Jonathan_Black@tomudall.senate.gov> wrote:

Friday, Monday, something like that.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 5:52 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Imports, FYI...

How near?

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:50 PM
To: Kaiser, Sven-Erik
Subject: RE: Imports, FYI...

I'd like to have a call on this issue in the near-future. Thanks.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, September 16, 2015 5:48 PM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Subject: RE: Imports, FYI...

thanks

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:45 PM
To: Jones, Jim; Kaiser, Sven-Erik
Subject: Imports, FYI...

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

Posted September 16, 2015

Tags:
cancer, carcinogens, chemcials, publichealth, righttoknow, saferchemicalshealthyfamilies, takeouttoxics, toxicchemicals, TSCA

The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue to overstate (see also here) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the Safer Chemicals Healthy Families coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of

assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances

when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet --regarding the reasonable potential of exposure to the fibers from any article or category of articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erinonite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

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Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the

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EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
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In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- *exactly what the agency should be doing under TSCA*. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/16/2015 9:51:56 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: Imports, FYI...

How near?

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Wednesday, September 16, 2015 5:50 PM
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To: Jones, Jim; Kaiser, Sven-Erik
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Daniel Rosenberg's Blog

What They Are Not Telling You: The Senate TSCA Bill Would Weaken EPA's Ability to Stop Importation of Products with Unsafe Chemicals

Print this page

Posted September 16, 2015

Tags:

cancer, carcinogens, chemcials, publichealth, righttoknow, saferchemicalshealthyfamilies, takeouttoxics, toxicchemicals, TSCA

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The Senate is poised to take up a bill to amend the Toxic Substances Control Act (TSCA), perhaps as early as next week. Supporters of the bill continue to overstate (see also here) the benefits of the legislation, while downplaying or ignoring its flaws - flaws that have led almost the entire environmental community to withhold its support, including more than 400 organizations that are part of the Safer Chemicals Healthy Families coalition. (NRDC is a member.) Supporters of the Senate bill generically claim that it will "protect America's families, especially children, from harmful chemicals that are present in everyday consumer products." But one key provision of the bill will actually make it *harder* for EPA to identify uses of chemicals of concern in everyday products, and to prevent their importation from overseas. And industry is pushing this precisely because EPA is finally starting to act to protect the public against imported products that contain toxic chemicals.

Those who recall the Senate mark-up of the bill may be surprised to hear this. At the mark-up, industry-written (or supported) language that weakened EPA's current import authority was removed from the bill, which was an important improvement. But as part of that deal, new language was added that weakens EPA's current authority under a different part of the law, but is designed to have a similar, and arguably worse, effect.

The current provision creates additional legal hurdles before EPA can require notification about products that contain toxic chemicals the agency believes could harm public health or the environment. The new provision is directed at EPA's authority to issue Significant New Use Rules (or "SNURs"). These are rules EPA issues when the agency wants advance notice about the new use of a chemical that could have potential to harm human health or the environment.

Under current law, one of the few effective steps EPA can take to protect the public is to require notice before a new use of a chemical is adopted, which EPA does by issuing a SNUR. A SNUR requires EPA to be notified at least 90 days before a significant new use of the identified chemical (or group of chemicals) begins. This gives EPA an opportunity to obtain more information if necessary and make a decision whether limitations should be imposed on the production or use of the chemical to protect public health or the environment. This kind of assessment cannot typically be done up-front, because EPA does not at that point have the information about the potential use, or the full universe of potential uses, to sufficiently analyze the hazards and exposures attendant to that new use. If EPA does not act within 90 days of receiving the notice, then the entity that submitted the notice is free to use the chemical as proposed.

EPA has issued about 2,000 Significant New Use Rules since TSCA became law. EPA estimates that it receives only about seven Significant New Use Notices (SNUNs) proposing new uses of those chemicals of concern, each year, and that after EPA evaluates information on the potential exposures resulting from the specific proposed use, many of these Notices expire without any restrictions being imposed on the proposed use of the chemical.

Although SNURs are deeply in the weeds of TSCA policy, they are an important means of informing the agency and protecting the public. They ensure that EPA has an opportunity to address the potential use of a chemical of concern *before* it causes problems to human health or the environment. Most SNURs are issued because EPA is concerned about the toxicity of a chemical and the potential harm to health and the environment that it may cause. SNURs can also serve as an important signal to the marketplace to move toward use of safer chemicals. Even if you never know it is there, the Significant New Use Program is operating to protect the public from greater exposure to unsafe chemicals.

So why are companies like Honda, Intel, and GE trying to weaken the program?

When EPA initially adopted its rules for how to implement the Significant New Use program in the early 1980s during the Reagan Administration, it adopted a default exemption for chemicals that were imported in "articles" (without going further down a legal and policy rabbit hole, an "article" essentially means a formulated item or product). The exemption was adopted on an extremely thin and flimsy rationale - literally one sentence -- which would not hold up to scrutiny if it was offered today: "This decision was made in response to a comment received on this issue and because the identified risks from uses of these substances in articles are not likely to occur." (49 FR 35017, September 5, 1984) Unsurprisingly, the one comment received promoting the default exemption for articles came from the Chemical Manufacturers' Association, which later rebranded itself as the American Chemistry Council. (Forget it, Jake, it was the Ann Burford era). As a result, for the vast majority of Significant New Use Rules issued by EPA, entities interested in importing a chemical of concern for a new use in an article have not been required to notify EPA in advance. In fact, until last year, out of some 2,000 Significant New Use Rules, EPA had only lifted the articles exemption for *two chemicals*: mercury and erionite fibers - a fiber with properties and health effects similar to asbestos.

However, despite the agency's default policy of excluding imported articles from reporting requirements for significant new uses, the agency has always retained its existing authority to lift the exemption "if EPA decides that review under a SNUR is warranted for specific substances...in articles." (79 FR 77897 ellipsis in original)

In recent years, it has become clearer to everyone - industry, EPA, state regulators and legislators, public health professionals, environmental groups, and academics and researchers of various types - that we are frequently exposed to chemicals of concern from many types of products (or "articles"), including those that we have in our homes, our workplaces, our schools, and in our modes of transportation. The scientific and popular literature is replete with examples of sources of human and/or environmental exposure including toys, carpets, clothes, seat cushions, furniture, cleaning supplies, computers, building materials and auto parts. These products have all been identified as potential sources of exposure to one or more problematic chemicals, including brominated flame retardants, formaldehyde, phthalates, non-stick and non-stain chemicals (perfluorinated), mercury, cadmium and a host of other substances.

In short, our understanding of how we are typically exposed to chemicals has expanded since the 1980s - and EPA has begun to shift its approach accordingly. The agency is starting to look more carefully at instances when the default exemption from Significant New Use Notification requirements for chemicals imported in articles should be lifted.

In December, EPA finalized a Significant New Use Rule for of benzidine dyes - these dyes have been found to break down into their component chemical, benzidine, which is classified as a *known human carcinogen*. "[T]he primary human health concern for consumers is exposure to the benzidine-based chemical substances through oral, dermal, or inhalation routes. Evidence from animal studies suggests that there is early life susceptibility to benzidine carcinogenesis. Cancer potency for benzidine was substantially increased when the dose was given in early life as compared to adults." (77 Fed. Reg. 18756, March 28, 2012)

Because of concern about the toxicity of the chemical EPA opted to "lift" the articles exemption, so that any proposed new uses of the benzidine dyes - including importing articles containing benzidine dyes -- will need EPA review and approval via a Significant New Use Notice.

"Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency's action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use." (77 Fed. Reg. 18758)

It is in reaction (and opposition) to these recent steps by EPA that industry is now pressuring Congress to revise TSCA and make it harder for EPA to require reporting of potential new uses of chemicals of concern imported in products. A lobbying entity called the Chemical Users Coalition, which comprises nine major corporations, has been lobbying to weaken EPA's authority under existing TSCA. The other member companies of the Chemical Users Coalition are: Procter & Gamble, Lockheed Martin, PPG, Hewlett Packard, IBM, and Boeing.

Under current law, EPA is authorized to designate a use of a chemical as a significant new use requiring notification after it has considered all relevant factors including:

- The projected volume of manufacturing and processing of the chemical;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical;
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of chemical.

These are all factors related to the form and substance of a chemical, the potential life cycle use of the chemical, and the potential for increased exposure from a new use of a chemical. The law does not now require a particular determination about the likelihood of exposure from a particular source, or product, or class of products.

The new provision goes well beyond these general factors for consideration, and imposes a new limitation on EPA - that it cannot impose a significant new use reporting requirement on an article being imported or processed in the U.S. unless the Administrator makes "an affirmative finding" that "the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule warrants notification."

Thus, under the new language in the Senate bill, EPA would now have to make a specified finding on a case-by-case basis on the "reasonable potential for exposure" before requiring notice of a new use of a chemical in an article or category of articles. This is a substantial shift in the burden of proof the agency must meet before obtaining simple notice about a potential new use of a chemical in an article. The new language gives the industry a stronger legal basis to challenge a significant new use requirement in court and raises the bar as to what the agency would have to show about the potential for exposure to a substance, prior to having any concrete information about the potential new use. In essence, the provision requires EPA to evaluate something before the agency even knows what it is. It also gives ammunition to EPA's frequent opponents in the inter-agency process, including OMB and the Small Business Administration Advocacy Office.

Currently, if EPA has a concern about the toxicity (health or environmental effects) of a chemical, and therefore a generalized concern about increased human or environmental exposure, it can adopt a new use notice requirement, including for new use in an article to be imported into the U.S. It may be that industry could successfully sue to overturn a significant new use requirement under the current language of TSCA, but it hasn't happened yet and there is no question that the new language raises the legal bar on EPA. Industry is seeking this language for a reason.

Some supporters of the Senate bill have argued that, while the new provision does change current law, it will have no practical effect on how EPA currently administers its SNUR program. This is incorrect. EPA would have a more difficult time adopting new use notice requirements under the new language in the Senate bill for the substances for which it has previously required notice of potential new use of a chemical in articles. For example, in its proposal to require notice for any new use of erionite fibers, EPA focused almost exclusively on the serious toxicity of the fibers ("In inhalation or injection studies in the rat and mouse, erionite fibers are more potent than crocidolite or chrysotile asbestos in inducing malignant mesothelioma." 56 FR 2890). EPA noted that there were no current known uses of the fibers in the U.S. and that, because of the serious health concerns the fibers raised, any new use, including importing in an article, would pose a risk of exposure and a potential health threat that warranted agency notice. EPA finalized a significant new use rule that applied to any new use, and "lifted" the articles exemption making the notice requirement applicable to imported articles. As a result, the public has been protected from any exposure to these cancer-causing fibers.

Under the new Senate language, EPA would now have to affirmatively identify any potential use of erionite fibers and then make a determination -- subject to legal challenge and judicial review if it made it through the OMB gauntlet --regarding the reasonable potential of exposure to the fibers from any article or category of articles before it could require notification of its potential new use in an imported article. If EPA neglected to correctly predict one or more potential uses of erinonite fibers -using crystal ball gazing technology for the 21st Century -- it could not then impose a new use notification requirement for those uses. Failure to imagine in advance *every potential use* would leave the public vulnerable to importation of new articles that the Administrator did not anticipate or predict.

Or consider EPA's recent significant new use rule for benzidine dyes, finalized last December. EPA identified the breakdown products of benzidine dyes as known human carcinogens, and referenced evidence of potential exposure from the dyes in clothes and textile-related uses. Based on the available information EPA had regarding the chemical's toxicity, and the potential for exposure from clothing, footwear and textiles, EPA imposed a new use notice requirement for any new use of benzidine dyes, and lifted the articles exemption, making the notice requirement applicable to potential new uses of benzidine dyes in articles (products) to be imported into the U.S.

Under the new Senate language, EPA *might* be able to issue the same notice requirement for use of benzidine dyes in clothes, footwear and textiles - as long as it could clear the new hurdle of demonstrating satisfactorily (to a court reviewing EPA's action in a legal challenge brought by industry) that it had identified a reasonable potential for exposure to benzidine dyes from each of those types of articles. But for any other articles, or category or articles for which EPA could not as easily identify a "reasonable potential for exposure" from the chemical -- for example, other categories of articles for which EPA did not already have some exposure information -- a court might rule that EPA did not have the authority to extend notice requirements to those uses, despite the agency's concerns about the chemicals' potential harm to health or the environment. Relying on the argument that EPA *might* prevail in such a lawsuit as an excuse for not flatly rejecting the proposed weakening of current law is simply irresponsible. The new Senate language in fact makes it more likely that articles containing chemicals of concern to EPA will be imported into the U.S. It is also directly contrary to what the drafters of the original TSCA intended.

In the Committee report filed when TSCA was originally passed in 1976, the Senate Commerce Committee (which handled TSCA then) noted the heightened concern about chemicals causing cancer, birth defects and

other harms to health and the environment and the limited scope of other existing laws that touched in various ways on the problem of chemical pollution including the Clean Air Act, Clean Water Act, Occupational Safety and Health Act and the Consumer Product Safety Act: "None of these statutes provide the means for discovering adverse effects on health and environment before manufacture of new chemical substances. Under these other statutes, the Government regulator's only response to chemical dangers is to impose restrictions after manufacture begins. The most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest....If hazards are to be discovered and prevented prior to the manufacture of new chemical substances or prior to the imposition of significant new uses of existing substances, premarket notification is an essential provision... the pre-market notification provisions of the committee bill forms [sic] the backbone of the preventive aspects of health protection sought by this legislation."

EPA is currently working on several other Significant New Use Rules, for which it also has proposed to lift the default regulatory exemption for new uses of the chemical in articles to be imported into the U.S. These include new use notice requirements for:

- (take a deep breath before you say this one) Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances (LCPFACs) - a group of substances that are persistent, bioaccumulative and toxic (PBTs);
- Toluene Diisocyanates (TDI) and related compounds - that are dermal and inhalation sensitizers that can cause asthma and lung damage;
- Hexabromocyclododecane (HBCD) - a flame retardant ingredient linked to hormone disruption, aquatic toxicity and a possible reproductive toxin that is already subject to authorization (meaning likely phase out) under the European Union's REACH regulation and a global phase-out under the Persistent Organic Pollutants (POPs) treaty;
- Polybrominated Diphenyl Ethers (PBDEs) - another group of flame retardants that are persistent, bioaccumulative and toxic.

In short, EPA is proposing to be notified before new uses of these chemicals - some of the "worst of the worst" that EPA has identified through its existing prioritization process - are introduced into the United States, including in the use of articles imported from China and other countries, to *prevent* people or the environment from being harmed by these toxic substances -- *exactly what the agency should be doing under TSCA*. EPA cannot possibly predict all the potential uses of these substances in advance -- or fully evaluate the hazards and risk of those that it can predict - without the information that the agency would receive in a significant new use notice from an entity seeking to use the chemical.

Efforts to limit EPA's ability to obtain information about potential new uses of chemicals of concern in products before they reach the market, are swimming against the tide of chemical regulation around the world, as well as consumer satisfaction and acceptance. Public demand (and therefore retailer demand) to know what chemicals are used in products is not going away. Contrary to the hopes of many in industry who are salivating for passage of the Udall/Vitter bill, flawed TSCA reform legislation will not stem that tide. EPA's existing authority to obtain information about potential new uses of chemicals of concern before they are imported into the U.S. in products is a modest and effective method of ensuring some degree of protection for the public. Constraining EPA's authority to target articles for significant new use notification is the industry's over-reaction to EPA's exercising its authority in a handful of instances. But increasing the burden on EPA and limiting its ability to take these steps will be met with its own reaction - more action at the state level, and in the marketplace - something these same industries should seriously contemplate before taking a step that could easily backfire.

Members of Congress who consider themselves supporters and protectors of EPA's role in protecting public health and the environment should carefully consider (or reconsider) their support for legislation containing this very problematic provision. If the Senate does not have the fortitude to tell these companies that this special interest provision to weaken current TSCA is an early Christmas gift that they cannot have, then the White

House should make clear that it needs to come out of the bill before TSCA reform legislation reaches the President's desk.